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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/030,194

08/15/2002

Michel Renard

218874USOPCT

8696

7590

05/08/2006

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EXAMINER

BAUM, STUART F

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/030,194

Applicant(s)

RENARD ET AL.

Examiner

Stuart F. Baum

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1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2005 and 21 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4-8 and 11-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-8 and 11-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/28/05</u>  | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The amendments filed 12/28/2005 and 2/21/2006 have been entered.
2. Claims 1, 4-8, 11-16, including SEQ ID NO:4, 5 and 6 are pending and are examined in the present office action.

Claims 12-16 have been newly added.

Claims 2-3, and 9-10 have been canceled.

3. Rejections and objections not set forth below are withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

### ***Oath/Declaration***

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. This objection is maintained for the reasons of record set forth in the Official action mailed 7/29/2005. Applicant's arguments filed 12/28/2005 have been fully considered but they are not persuasive.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Applicants contend that Mr. Pierre Barret modified his address, but did not initial and date the modification. Applicants contend that Mr. Barret did signed and date in the same box as the modification, thus qualifying as an initialed and dated alteration (page 14 of Remarks, 1<sup>st</sup> full paragraph).

The Office contends that all alterations to the Inventors name, address, etc, require that they be initialed. See 37 CFR 1.52(c).

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 4-8, 11 and 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection includes dependent claims.

Claim 1 is indefinite for reciting "(II, SEQ ID NO:6): Gly Tyr X1 Val Glu X2 (II) in which X1 is as defined above and X2 represents a basic amino acid". Applicants have listed an amino acid sequence which is denoted as "II" wherein X2 represents a basic amino acid, and Applicants also denote this sequence as SEQ ID NO:6. In the sequence listing, SEQ ID NO:6 is Gly Tyr Xaa Val Glu Xaa in which Xaa = any amino acid except Glu. It is not clear what is Applicants' intention in regards to the identity of the last amino acid in the six amino acid polypeptide given that Applicants refer to it as II or SEQ ID NO:6 in the claim.

### ***Written Description***

7. Claims 1, 4-8, 11 remain rejected and claims 12-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 7/29/2005. Applicant's arguments filed 12/28/2005 have been fully considered but they are not persuasive.

Applicants contend that the GRAS family was known at the time of filing the present invention and that this family is characterized by several conserved motifs (page 7 of Remarks, 2<sup>nd</sup> paragraph). Applicants submit two references that discuss GRAS family proteins:

Pysh et al (1999, The Plant Journal 18(1):111-119); listed in IDS

Schumacher et al (1999, PNAS 96:290-295); listed in IDS

Applicants contend that the motif (GYRVEEE or GYNVEE) is only present in a sub-group of GRAS family proteins, BZH, GAI, RGA, and RGAL proteins, each of which is involved in plant height (page 7 of Remarks, 2<sup>nd</sup> paragraph). Applicants also submit Peng et al (1999, Nature 400:256-261) which disclose GRAS family proteins involved in regulation of plant height in wheat and maize and which contains the motif GYRVEE in maize or the motif GYKVEE in wheat. Applicants contend that a substitution of the C-terminal glutamic acid by a basic amino acid in any of the disclosed proteins will probably result in a reduction in plant size (paragraph bridging pages 7 and 8 of Remarks).

The Office contends that GAI and RGA may be involved in a similar developmental processes, for example, plant height, but they are not homologous genes, as evidenced by their names, GIBBERELLIN INSENSITIVE (GAI) and REPRESSOR OF GAI (RGA) (Shumacher et al, page 292, right column, 3<sup>rd</sup> paragraph); RGA is a repressor of GAI. Therefore, the two proteins have different biochemical activities and therefore should not be compared or presented

as representative sequences for satisfying the written description requirement, even though they share a six amino acid domain.

The Office contends that the maintenance of the rejection is also in part due to Applicants' recitation of "basic amino acid". It is the position of the Patent Office to give the broadest reasonable interpretation of the claims. In the instant case, Applicants have not defined "basic amino acid" either in the claims nor in the specification. The Office contends that "basic amino acid" could mean any amino acid, for which "basic" is defined as *fundamental* (Merriam-Webster Dictionary, on-line, 2006) or it could mean one of three amino acids which are considered basic, i.e., Arginine, Lysine or Histidine (Campbell et al (Ed's), 2002, BIOLOGY, 6<sup>th</sup> Edition, Benjamin Cummings, Publisher, New York, pg 73). Applicants have not defined this term anywhere in the specification or claims. Applicants have not given any indication as to the intended meaning of "basic amino acid" and therefore, the Office broadly interprets this recitation to mean any amino acid. The Office contends that Applicants have not disclosed a representative number of sequences encoding proteins comprising this domain or disclosing other domains that are necessary and sufficient for replicating the activity of Applicants' SEQ ID NO:4.

The Office contends that the claimed amino acid sequence is a mutant form of the wild-type sequence and that when the native wild-type protein is mutated in the specific locations as claimed, the plant exhibits a mutant phenotype, i.e., a reduced height. The Office contends that because Applicants are claiming a domain of a protein and not the whole protein, their claim is broadly interpreted to read on a genus of sequences of which Applicants have not disclosed. Applicants have only disclosed one sequence from rapeseed. The Office contends presenting

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other proteins that comprise the wild-type domain of Applicants' SEQ ID NO:5 does not constitute a disclosure of a representative number of sequences because the disclosed sequences do not have a mutant domain and would not give the expected phenotype when transformed into a plant. In addition, the disclosed proteins have not been shown to produce a protein with the same activity as Applicants' disclosed protein of SEQ ID NO:4 when mutated as disclosed above, and RGA and RGAL proteins are not homologues of Applicants' SEQ ID NO:4. Therefore, presenting conserved domains of GRAS family proteins does not satisfy the written description requirement because not all GRAS family proteins have the same activity/function as Applicants SEQ ID NO:4.

### *Enablement*

8. Claims 1, 4-8, and 11 remain rejected and new claims 12-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 7/29/2005. Applicant's arguments filed 12/28/2005 have been fully considered but they are not persuasive.

Applicants contend that "the mere filing of a patent application serves as conception and construction reduction to practice the subject matter described in the application (MPEP §2138.05. Moreover, MPEP §2138.05 states: the inventor need not provide evidence of either conception or actual reduction to practice when relying on the content of the patent application" (page 8 of Remarks, 4<sup>th</sup> paragraph).

The Office contends that as further stated in MPEP §2138.05, “Constructive reduction to practice requires compliance with 35 U.S.C. 112, first paragraph”. The MPEP further states “Proof of a constructive reduction to practice requires sufficient disclosure under the “how to use” and “how to make” requirements of 35 U.S.C. 112, first paragraph. The Office notes that Applicants are citing the MPEP from the section dealing with 35 U.S.C. 102(g) and not from MPEP §2164, “The Enablement Requirement”.

Applicants contend that the specification provides a detailed explanation of how to clone, express and characterize polynucleotides that fall within the scope of the present invention (page 9 of Remarks, 1<sup>st</sup> paragraph). Applicants contend, that given the teachings in the specification and the teachings of Pysh et al, Schumacher et al and Peng et al, one of skill in the art would be able to identify sequences containing the motif of sequence (I) and would be able to produce mutations in this sequence to effect a change in plant size (page 9 of Remarks, 1<sup>st</sup> and 2<sup>nd</sup> paragraph).

The Office contends that the test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue (MPEP § 2164.01). In the present case, the Office asserts that the amount of experimentation is undue given the breadth of the claims, the state of the prior art, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. The Office contends that Peng et al (Nature, July 15, 1999 400:256-261; listed in IDS) discloses that mutations in “gai can generate apparent loss-of -function derivative alleles which confer a tall, rather than dwarf phenotype” (page 259, right column, 2<sup>nd</sup> full paragraph). The Office contends that Applicants’



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cited reference is another example of unpredictability in the art. The Office contends that Applicants have not disclosed how transforming a plant with their invention can create a dominant negative mutation that over-rides the wild type gene. Therefore, given the level of unpredictability in the art, the lack of disclosure by Applicant, the breadth of the claims, the state of the prior art, the lack of working examples, undue trial and error experimentation would be required by one of skill in the art to make and/or use the broadly claimed invention. The invention is not enabled.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Foisset et al (1995, Theor. Appl. Genet. 91(5):756-761, listed in the IDS).

The claims are drawn to a mutant plant with reduced development, wherein said mutant plant is obtained by chemical mutagenesis and comprises one or more copies of a nucleic acid sequence of claim 1, or wherein the plant is a rapeseed plant, or a descendant of said mutant plant comprising one or more copies of said nucleic acid sequence.

Foisset et al disclose a dwarf Brassica napus plant comprising a mutant *breizh* (*bzh*) gene. Foisset et al disclose that a chemical mutagenesis was used to mutagenize seeds (page 757, "Origin of the Bzh gene"). Foisset et al disclose crosses were made which encompass claims drawn to "A descendant" (*Ibid*). Because of Applicants' own admitted statement "The inventors have now characterized and sequenced the *BZH* gene of *B. napus*, and its mutant allele *bzh*, associated with the dwarf phenotype previously observed by Foisset et al (1995, ...)" (page 3,

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lines 30-33), the mutant gene of Foisset et al comprises Applicants' claimed invention, and as such, Foisset et al anticipate the claimed invention.

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

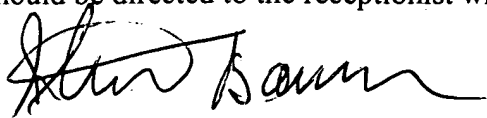
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read "Stuart F. Baum". The signature is fluid and cursive, with the first name "Stuart" and last name "Baum" clearly distinguishable.

Stuart F. Baum Ph.D.

Patent Examiner

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April 27, 2006

STUART F. BAUM, PH.D.  
PATENT EXAMINER